z-kat, inc.

DEC - 4 2000

K002893

2903 simms street hollywood, florida 33020 tel: 954.927.2044 fax 954.927.0446 zkat@z-kat.com www.z-kat.com

510(K) SUMMARY

SUBMITTER: Z-KAT, Inc.

ADDRESS: 2903 Simms Street

Hollywood, FL 33020

PHONE NUMBER: 954-927-2044

FAX NUMBER: 954-927-0446

CONTACT PERSON: William F. Tapia

DATE PREPARED: September 14, 2000

TRADE NAME: FluoroLab Plus

COMMON NAME: Stereotaxic Instrument

CLASSIFICATION NAME: Class II

SUBSTANTIAL EQUIVALENCE CLAIMED TO:

1. The Fluorotactic Guidance System, Mk I, Z-KAT, Inc., K984298
2. StealthStation, Sofamor Danek, K954276
3. FluoroNav, Sofamor Danek, K990214
4. The Voyager; Marconi Medical Systems, K000310
5. VectorVision^2, BrainLab, K962939

DESCRIPTION:

FluoroLab Plus is an integrated system that helps a surgeon more accurately position drill guides, screw drivers, needles, and other surgical instruments using at least two captured fluoroscopic images. The acquired images are displayed on a flat panel monitor. Surgical tools are instrumented with LEDs or small reflective markers. The position and orientation of the surgical tool is continuously tracked by an optical camera and updated in reference to the fluoroscopic images to provide constant navigational guidance to the target.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

FluoroLab Plus will consist of following components:

K002893

September 14, 2000

1) Registration artifact

2) Fluoroscopic image intensifier system (C-arm)

3) Personal computer (PC) with a Data Translation image acquisition card and one flat panel monitor

4) Coordinated Fluoroscopy

5) Optical camera

6) Tools and accessories - surgical tools instrumented with LEDs or reflective markers

A registration artifact, which is transparent to X-rays, will be placed over the patient in proximity to the desired surgical area. This artifact has small steel balls embedded such that when the C-arm is used to capture images of the area, the balls will create fiducial shadows on the image. The shadows on the acquired image will be used for registration. At least two images will be required, an Anterior/Posterior (A/P) view and a Sagittal view.

The PC will receive the image data from the C-Arm and display it on the flat panel monitor. The surgeon will navigate his tools to the desired target by simultaneously observing the tool's graphical representation on the monitor and physically manipulating the tracked surgical instruments into position.

INTENDED USE:

FluoroLab Plus will be used for navigational guidance to position instruments during surgical procedures. It will provide a method of navigational guidance of tools through the use of a standard C-arm fluoroscope to capture images and an optical camera for instrument tracking. This increase in control will free the surgeon from the iterative process conventionally used, reduce the length of the surgical procedure, and enable minimally invasive procedure. In addition, since only two fluoroscopic images are needed, the exposure to X-rays is greatly reduced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Mr. William F. Tapia
Chief Operating Officer, Acting Director of
Quality Assurance/Regulatory Affairs
Z-KAT, Inc.
2903 Simms Street
Hollywood, Florida 33020

Re: K002893
Trade Name: Fluoro Lab Plus
Regulatory Class: II
Product Code: HAW
Dated: September 14, 2000
Received: September 18, 2000

Dear Mr. Tapia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

z-kat, inc.

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INDICATIONS FOR USE

510(k) Number (if known): K002893

Device Name: FluoroLab Plus

Indications for Use:

FluoroLab Plus will be used to assist in the alignment of surgical instruments by providing the surgeon with intraoperative navigational guidance based on pre-acquired fluoroscopic images. This system will use coordinated-fluoroscopy to allow intra-operative planning of the alignment of surgical tools such as a screw, nail, or needle.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002893